

Remarks

Claims not corresponding to the elected invention have been canceled. One of the canceled claims, claim 56, appears to have been included in the elected (and examined) invention in error, as this claim depends from claim 50, which was restricted as belonging to a different and separately patentable invention.

New claims 65-76 have been added. These claims substantially correspond, respectively, to original claims 6, 8, 11-14, 16, 22-24, 53 and 55. The new claims depend from claims in the restriction group elected by Applicant, but were previously canceled. Thus, these claims are added to restore claims of the present invention that were previously canceled. No new matter has been added.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-5, 7, 9, 10, 15, 21, 52, 54, and 56 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description. Applicant has amended the claims and respectfully requests reconsideration.

The Examiner indicated that the recitation of “functional variants” in claims 1-4 was broad whereas the application disclosed only a limited number of such variants.

Applicant has amended the claims to recite that functional variants comprise 2 or fewer amino acid substitutions. Support for this amendment is found in the application, e.g., at page 13, lines 3-5.

Applicant notes that the Examples contain a working example of a functional variant, SEQ ID NO:62. Example 7 shows mutation of the two cysteine residues of the EphA3 HLA class II binding peptide, at positions 5 and 8 of the core peptide (SEQ ID NO:53). As demonstrated in Example 7, the effect of mutating the two cysteines was not identical; whereas cysteine residue at position 8 of SEQ ID NO:54 (equivalent to position 5 of SEQ ID NO:53) appeared to be required for efficient recognition by T cell clone, mutation of the cysteine at position 11 of SEQ ID NO:54 (equivalent to position 8 of SEQ ID NO:53) was not only tolerated, but in fact resulted in a functional variant peptide (SEQ ID NO:62) that was more efficiently recognized by T cells than the normal (unmutated) peptide.

Thus Applicant has provided not only descriptive language in the specification but also a working example that is illustrative of the type of mutations tolerated in the EphA3 peptide in generating functional variants.

Applicant believes that the specification teaches one of ordinary skill in the art that Applicant was in possession of the invention as now claimed. Applicant has provided much more than a “mere wish or plan” and therefore respectfully requests that the Examiner reconsider the written description rejection.

The Examiner rejected claims 1-5, 7, 9, 10, 15, 21, 52, 54, and 56 under 35 U.S.C. § 112, first paragraph, as not enabled. Applicant has amended the claims and respectfully requests reconsideration.

The Examiner acknowledged that the application is enabling for isolated peptides that consist of a fragment of EphA3 (SEQ ID NOs:3, 5 or 7), wherein the fragment comprises SEQ ID NOs:51, 52, 53, 54 or 62. Applicant agrees that the application enables at least this much.

The Examiner objected, however, to the enablement of functional variants and to the enablement of polypeptides that comprise “additional flanking residues that are not part of SEQ ID NO: 3, 5, or 7”. Office Action at page 4.

Applicants have amended the claims to restrict the scope of functional variants to those that have 2 or fewer (i.e., 1 or 2) amino acid substitutions. As noted above, Applicant has provided a complete description of how to make functional variants, including a working example in which a specific functional variant of greater activity (SEQ ID NO:62) was identified. Of the 9 amino acids in SEQ ID NO:53, two have been tested by Applicant. Applicant submits that it would not be undue experimentation for one of ordinary skill in the art to alter the amino acid sequence of the peptide at the other 7 residues of SEQ ID NO:53 to identify additional functional variants within the scope of the claims. Peptide synthesis is entirely routine in the art, and given the high level of skill in the art and the guidance in the specification regarding both the amino acid sequence and methods for testing HLA class II peptides, one of ordinary skill in the art would practice merely routine experimentation to identify additional functional variants.

Regarding the addition of flanking residues that are not part of SEQ ID NOs:3, 5 or 7, Applicant respectfully urges reconsideration. As described in the specification, it is well known

that proteins comprising HLA binding peptides are processed to yield the peptides in a final form for presentation by HLA molecules (see page 11 of the specification, for example). It is also well known in the art to make fusion proteins. Specific types of fusion proteins are expressly contemplated in the application, such as those comprising EphA3 HLA class II binding peptides and endosomal targeting signals, and those comprising EphA3 HLA class II binding peptides and other HLA class I or HLA class II peptides (polytopes). The addition of flanking residues (e.g., to an EphA3 HLA class II binding peptide) in the sense of a fusion protein is very well known in the art and therefore no undue experimentation would be required of one of ordinary skill in the art to practice the invention as is now claimed.

Applicant submits that the guidance provided in the application, in combination with the high level of skill in the art and the routine nature of the techniques used in this type of experimentation, compels a conclusion that one of ordinary skill in the art would require only routine experimentation to make and use other functional variants as are now claimed.


In view of the claim amendments and arguments presented above, Applicant respectfully requests that the Examiner withdraw the rejection of the claims under 35 U.S.C. 112, first paragraph.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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